Key messages

- Molecular diagnosis of *Neisseria gonorrhoeae* is feasible in a routine diagnostic setting for genitourinary medicine attendees. Provided that positive results are confirmed by repeated testing of the sample, the Becton Dickinson strand displacement assay (BD ProbeTec SDA) is both sensitive and specific
- Molecular diagnosis of *N gonorrhoeae* provides rapid results and allows the use of non-invasive samples (first void urine in men), with benefits for workflow in both the laboratory and the clinic
- A differential protocol which includes a sample for *N gonorrhoeae* culture from those with a listed risk factor for *N gonorrhoeae* infection will allow a *N gonorrhoeae* isolate to be available for antibiotic sensitivity testing

culture screens by half, allowing the laboratory to concentrate on cultures from those patients who are likely to be positive.

A post-implementation audit confirmed that the protocol can be easily followed in a busy GUM clinic and had actually achieved a reduction of 59% in culture submission. We found that the protocol was followed well in patients with a listed risk factor, but some patients without a listed risk factor also had culture specimens (contrary to the protocol) submitted.

We also found that there was no difference before and after implementation of *N gonorrhoeae* SDA test, in the prevalence of *N gonorrhoeae* infection (3.4% and 3.2%) or the number of patients with *N gonorrhoeae* infection who have a listed risk factor for acquiring infection (92.5% and 92%) in the population studied. Our post-implementation audit confirmed the high concordance in results between FVU SDA and urethral swab cultures in males, and SDA and culture both on endocervical swabs in females. Whenever the diagnosis of *N gonorrhoeae* infection was made on the basis of culture alone, it was from a site other than urethral (male) and endocervix (female), this emphasises the relevance of continuing to sample other anatomical sites as indicated by sexual practice. Only 1 of 44 (2%) female patients had infection at the urethral site alone, and this was consistent with our earlier finding. Interestingly, our post-implementation audit showed that only 5% of the positive patients or 0.15% of the tested population required a recall for *N gonorrhoeae* culture prior to initiating treatment, compared with the projected figures of 7% and 0.25%, respectively, on the basis of the initial study.

The implementation of this test into our routine clinical practice from February 2005 has contributed to changes in many areas of our clinical practice. Less time spent on microscopy and not having to take urethral swabs from the majority of male attendees has allowed us to significantly increase our clinical throughput, and we have been able to use the SDA test as part of a fast-track clinic for screening asymptomatic patients. A recent audit of clinical practice has shown that between May 2005 and November 2005, 48 h access has improved from 24% to 40%. We also found that turnaround time for negative results improved as these were reported the next day rather than after 48 h of culture. Another benefit was the increase in acceptability of the test by male patients (especially in the asymptomatic men) because of testing via non-invasive FVU.

Our experience shows that NAAT screening can be successfully introduced in a routine GUM setting for screening *N gonorrhoeae* infection without the loss of epidemiological data on sensitivity of the organism. A NAAT screening protocol for *N gonorrhoeae* infection, as implemented by us, has many advantages like improved turnaround time for negative results, increased patient throughput in the clinic because invasive urethral sampling in men can be avoided and acceptability of screening for *N gonorrhoeae* infection, especially in men because of the non-invasive sampling. Furthermore, as the NAAT screening can be automated, it allows the laboratory to concentrate on culture samples from patients likely to yield a positive result.

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REFERENCES

1 **Health Protection Agency**. *HIV and other sexually transmitted infections in the UK 2005*, http://www.hpa.org.uk/publications/hiv_sti_2005/default.htm.
2 **Van Dyck E**, Leven M, Pattyn S, *et al*. Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by enzyme immunoassay, culture, and three nucleic acid amplification tests. *J Clin Microbiol* 2001;**39**:1751–6.
3 **Boyadzhyan B**, Yashina T, Yatabe JH, *et al*. Comparison of the APTIMA CT and GC assays with the APTIMA combo 2 assay, the Abbott LCx assay, and direct fluorescent-antibody and culture assays for the selection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. *J Clin Microbiol* 2004;**42**:3089–93.
4 **Health Protection Agency**. *The gonococcal resistance to antibiotics surveillance programme. Annual report 2004*. London: Health Protection Agency, 2004.
5 **De Silva T**, Kudesia G, Joall A, *et al*. Significance of low positive scores obtained with a method other than acceleration in the BD ProbeTec-Strand displacement amplification test for detection of *Neisseria gonorrhoeae*. *J Clin Microbiol* 2006;**44**:4628–9.
6 **Barlow D**, Phillips I. Gonorrhoea in women. Diagnostic, clinical and laboratory aspects. *Lancet* 1978;**1**:761–4.

COMMENTARY

Developments in diagnostic techniques that demonstrate significant advantages on robust evaluation should be welcomed into clinical practice. Nucleic acid amplification tests (NAATs) are already widely used in North America and some European countries for the detection of *Neisseria gonorrhoeae* infection, often as a combined chlamydia/gonococcal (GC) test at little or no extra cost. There are important drivers why these tests should be more widely used—they are highly sensitive, they facilitate modernisation of service delivery in genitourinary medicine (GUM) clinics, they enable screening in community settings with specimens collected by patients and they are amenable to automated processing. Culture still remains necessary for surveillance of antimicrobial resistance,

confirmatory testing and testing at non-genital sites (rectum and pharynx).

In this issue, Ryan *et al*[1] validate the BD Probe Tec assay and describe an algorithm using this assay as the standard test for detection of *N gonorrhoeae* at genital sites in a GUM clinic setting. Microscopy is still used as a rapid test, but selectively for patients with symptoms or a specific risk factor for gonorrhoea. Culture is maintained, but again used selectivity for patients with symptoms, those at higher risk of gonorrhoea (men who have sex with men, past infection with gonorrhoea or contacts of gonorrhoea) and for testing at non-genital sites. The reported outcome of this approach is increased sensitivity of gonorrhoea detection, confirmation by culture for most infections and reduced laboratory processing of negative culture plates. The study also offers further reassurance on the specificity of GC NAATs when supported by supplementary testing, as has recently been reported in a population with low prevalence of gonorrhoea.[2]

Should the Sheffield algorithm be widely adopted by GUM clinics? Might alternative testing protocols be more appropriate? Could dual testing by NAAT and culture be reduced further? Screening men for urethral infection by a combined GC/chlamydia NAAT on urine with an additional urethral culture test taken from those who are sexual contacts of gonorrhoea or who have symptoms or signs of urethral discharge would seem fairly straightforward. Asymptomatic and untreated men testing positive in the NAAT would be reassessed by culture and then receive antimicrobial treatment. In women, genital tract GC infection is frequently asymptomatic. Infection may be confined to the urethra. Vaginal discharge is a common symptom, with poor sensitivity and specificity for this infection. Do cultures really need to be taken for all symptomatic women? Further debate is needed and more experience needs to be gained on the relative effectiveness of taking cultures using a ''best-guess'' approach as against greater reliance on recall and reassessment. History shows that the UK was slow to implement molecular tests for the detection of genital-tract chlamydial infection. With appropriate strategies and quality assurance, the time is surely right to move forward with GC NAATs.[3]

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REFERENCES

1 **Ryan C**, Kudesia G, McIntyre S, *et al*. BD Probe Tec ET assay for the diagnosis of gonorrhoea in a high risk population: a protocol for replacing traditional microscopy and culture techniques. *Sex Transm Infect* 2007;**83**:175–9.
2 **Lavelle SJ**, Jones KE, Mallinson H, *et al*. Finding, confirming and managing gonorrhoea in a population screened for chlamydia using the Gen-Probe Aptima Combo2 assay. *Sex Transm Infect* 2006;**82**:221–4.
3 **Ison C**. GC NAATs: is the time right? *Sex Transm Infect* 2006;**82**:515.